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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,263	12/28/2001	Akira Matsumori	2001-1881A	1315

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EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/019,263	Applicant(s) MATSUMORI, AKIRA	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 27, 28 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 27, 28, and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a 371 of PCT/JP00/04286, filed June 28, 2000. this application also claimed priority to Japan 185297/1999, filed June 30, 1999.

Applicant's amendments filed December 24, 2003 have been entered. The cancellation of claims 26, 29-32, and 34-36 is acknowledged.

Claims 25, 27, 28, and 33 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 27, 28, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. (WO 98/37875, its English translation US Patent 6,277,888 is provided in the IDS received March 27, 2002) in view of Merck (The Merck Manual, 16th ed., 1992, page 2370-2371).

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Sakai et al. teaches 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol or its hydrochloride salt is useful in treating viral hepatitis such as hepatitis B, non-A/non-B hepatitis (See col. 2, lines 37-38; col. 5, line 28-39). Sakai et al. also teaches that the herein claimed compound is useful as treating infectious diseases caused by pathogenic microorganisms (see col. 4, line 27-28; also col. 5, lines 41-44). Sakai et al. teaches 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating necrosis induced by toxin or the viral hepatitis (See col. 5, line 38). Sakai et al. teaches 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating eye disease such as conjunctivitis (See col. 4, lines 51-59).

Sakai et al. does not expressly teach 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is useful in treating viral myocarditis caused by hepatitis virus, orthomyxovirus or picornavirus.

Merck teaches conjunctivitis can be caused by enterovirus, which belongs to the family of picornavirus (See page 2370).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol or its hydrochloride salt to treat viral myocarditis caused by hepatitis virus, orthomyxovirus or picornavirus.

One of ordinary skill in the art would have been motivated to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol or its hydrochloride salt to treat viral myocarditis caused by hepatitis virus, orthomyxovirus or picornavirus. 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is known to be useful in treating infectious diseases

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and hepatitis B infection (i.e., viral infection caused by hepatitis B virus in the liver). Therefore, employing 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol to treat viral myocarditis caused by hepatitis B virus, which is viral infection caused by hepatitis B virus in the heart muscle, would have been reasonably expected to be effective since the causative agent is hepatitis B virus, absent evidence to the contrary. Furthermore, one of ordinary skill in the art would have been motivated to employ 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol to treat viral diseases caused by orthomyxovirus or picornavirus. Since the herein claimed compound is known to be useful in treating conjunctivitis, which is a condition caused by picornavirus (conjunctivitis), employing the herein claimed compound in treating diseases caused by picornavirus, such as the infection in the heart (myocarditis), would be reasonably expected to be useful.

Response to Arguments

Applicant's arguments filed December 24, 2003 averring the herein claimed compound's effectiveness of treating hepatitis depending on the liver regeneration and/or promoting hypertrophy and hyperplasia of hepatocytes have been fully considered but they are not persuasive. Examiner notes that the herein claimed compound is also known to be useful in treating various viral infectious disease. Furthermore, Sakai et al. does not exclude the effectiveness of the herein claimed compound against hepatitis virus. Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would have reasonably expected to employ the herein compound in the treatment of viral myocarditis as recited.

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Applicant's arguments filed December 24, 2003 averring the herein claimed compound's effectiveness of treating eye diseases only, but not myocarditis simply because they are different diseases have been fully considered but they are not persuasive. Examiner notes that the herein claimed compound as useful in treating infectious diseases and conjunctivitis, which is known to be caused by picornavirus. Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would have reasonably expected to employ the herein compound in the treatment of viral myocarditis as recited.

Applicant's arguments filed December 24, 2003 averring the cited prior art's failure to provide reasonable expectation of success have been fully considered but they are not persuasive. As discussed above, the herein claimed compound is known to be useful in treating viral diseases including viral diseases caused by hepatitis virus and picornavirus. Although the cited prior art fails to expressly teach the usefulness of the herein claimed compound in treating viral infection of the heart, employing the herein claimed compound in treating viral infection caused by hepatitis virus and picornavirus in the heart (myocarditis), would be reasonably expected to be useful.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

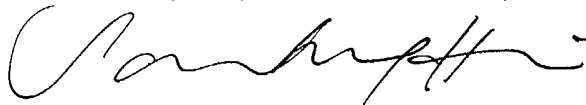
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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San-ming Hui
Patent Examiner
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